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Action (copy enclosed), Applicant submits that a Sequence Listing is not required for the above-identified application since the D-amino acid sequences listed throughout the Specification of said application are all excluded under 37 CFR §1.821(a)(2). Applicant respectfully requests that the Examiner specify the location, by page number, those amino acid sequences encompassed by 37 CFR §§1.821-1.825.

2. Claims 1-46 were rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In particular, the claims were found to be confusing and unclear as to the meaning and scope of "heterochain polymer". The Examiner opined that the objectionable term is not recognized in the art.

Applicant respectfully contends that a person skilled in the art would recognize the term "heterochain polymer". In support thereof, applicant submits that the U.S.P.T.O. has issued 10 patents containing the term "heterochain polymer." A copy of the U.S.P.T.O. website reporting the results of a Boolean search of the term "heterochain polymer" in the patent database, is submitted herewith. Further, the *IUPAC Compendium of Chemical Terminology*, 2<sup>nd</sup> Ed., Alan D. McNaught and Andrew Wilkinson, Eds., Royal Society of Chemistry, Cambridge, UK, 1997, defines

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"heterochain polymer" as "a class of polymer in which the main chain is constructed from atoms of two or more elements." A copy of the website page maintained by the Royal Society of Chemistry containing the definition of "heterochain polymer" is submitted herewith. Finally, the Specification of the above-referenced application, provides a number of specific examples of "absorbable heterochain polymer[s]". Based on the foregoing evidence, Applicant submits that the Examiner has not met the burden of presenting, by a preponderance of evidence, why a person skilled in the art would not recognize the meaning of the term "heterochain polymer" as required by *In re Wertheim*, 541 F.2d 257, 262, 191 USPQ 90, 96 (CCPA 1976). Applicant respectfully requests that the 35 U.S.C. §112, second paragraph, rejection be withdrawn.

3. Claims 1-46 were rejected under 35 U.S.C. §103(a) as "obvious" based on the disclosures of Shalaby et al. (U.S. 5,665,702 or U.S. 5,672,659) in view of Auer et al. (WO 92/11844). The Examiner alleges that it would have been *prima facie* obvious to "to provide the polymers of Shalaby et al. in the form of a microsphere as suggested by Auer et al. to obtain the function of a microsphere form. Immobilizing the peptide on the microsphere would have been obvious to provide ready access to the polypeptide for reaction with another substance."

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Applicant respectfully disagrees with the relevance of Auer et al. Auer is directed to a *method* of stabilizing a biologically active protein by *complexing* it with a polycation. Auer does not discuss bound microparticles in which a biologically-active peptide is immobilized on the surface of an absorbable heterochain polymer. To the contrary, the Auer microspheres can not contain the peptide on their surface. According to Auer, microspheres containing a protein-polycation complex can be prepared using a 2-part process. See Auer et al. pages 7-9. In the first step of the Auer process, a protein-polycation complex is atomized into small particles, according to the process described by Gombatz et al. The protein-polycation microparticles are then **incorporated into** or **encased by** a biodegradable polymer using the procedures outlined again by Gombatz, et al. The 2<sup>nd</sup> phase of the Auer process produces biodegradable microparticles *containing* the biologically-active agent with the polymer. Unlike the microparticles of the above-referenced application, the biologically active agent of the microparticles of Auer **does not bond with the polymer**, but instead interacts with **a biological polycation**, examples of which are poly(lysine) and poly(arginine). See Auer et al. page 6, lines 20-21. Auer describes the interaction between the biological agent and the polycation as "electrostatic" in nature, See Auer et al. page 6, lines 8-9, which are dissimilar to the

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**ionic** interactions that immobilize the biologically-active peptide **on** the surface of the heterochain polymer like the novel microparticles of the present application. See present application at page 13, line 35. Applicant contends it would not have been apparent from Auer that a biological agent could be immobilized on the surface of the polymer of the microsphere.

The two Shalaby patents do not teach or suggest the novel bound microparticles of the above-referenced application.

Applicant respectfully contends that based on the foregoing, the Examiner has failed to establish a *prima facie* case of "obviousness" under 35 U.S.C. §103(a). The Court of Appeals for the Federal Circuit has established the criteria for a finding of obviousness as follows:

Uniroyal, Inc. v. Rudkin-Wiley Corp., 837 F.2d 1044, 1051-52, 5 USPQ 1434, 1438 (Fed. Cir. 1988), cert. denied, 109 S.Ct. 75 (1988), on remand, 13 USPQ2d 1192 (D.Conn. 1989), "something in the prior art as a whole must suggest the desirability, and thus the obviousness, of making the combination."; *In re. Stencil*, 828 F.2d 751, 755, 4 USPQ2d 1071, 1073 (Fed. Cir. 1987), "obviousness can not be established 'by combining the teachings of the prior art to produce the claimed invention, absent some teaching or suggestion that the combination be made.'"; *Alco Standard Corp. v. Tennessee Valley Authority*, 808 F.2d 1490, 1498, 1 USPQ2d 1337, 1343 (Fed. Cir. 1986), cert. denied, 108 S.Ct. 26 (1987), "the question is not simply whether the prior art 'teaches' the particular element of the invention, but whether it would 'suggest the desirability, and thus the obviousness, of making the combination.'"; *Carella v. Starlight Archery*, 804 F.2d 135, 231 USPQ 644 (Fed. Cir. 1986); *ACS Hospital System, Inc. v. Montefiore Hospital*, 732 F.2d 1572, 221 USPQ 929 (Fed. Cir. 1984), "obviousness can not be

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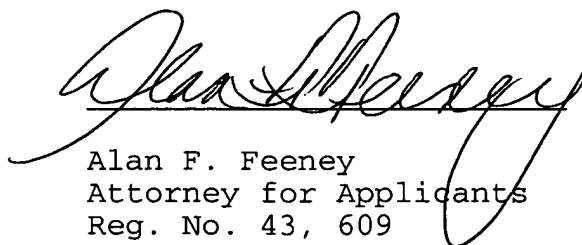
established by combining the teachings of the prior art to produce the claimed invention, absent some teaching or suggestion supporting the combination. Under section 103, teachings of references can be combined only if there is some suggestion or incentive to do so."

Donald S. Chisum, Patents, A Treatise on the Law of Patentability, Validity and Infringement, Vol. 2, 5-218, 1992, (emphasis added). Applicant respectfully submits that Shalaby et al. do not provide the proper motivation to combine their teachings with those of Auer et al., nor do Auer et al. provide the requisite motivation to combine their teachings with the teachings of Shalaby et al. As such, the rejection of all claims under 35 U.S.C. §103(a) should be withdrawn.

Based on the foregoing, Applicants believe that all pending claims are in condition for allowance. Prompt and favorable action is earnestly solicited.

Respectfully submitted,

Date: 3-31-2003

  
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